

REMARKS

Claims 31-44 will be pending in this application after entry of the foregoing amendments. Claim 31 is the only pending independent claim and is a generic claim with respect to the amendment reciting biguanide ISIS with the formula for the biguanide and its broadly-recited alkyl and aromatic derivatives, as supported respectively in paragraphs [0062] and [0021] of the application as filed.

Claim 34 depends from claim 31 and further recites the formula for a biguanide and its derivatives and salts thereof. Support for the amendment may be found in paragraphs [0027] and [0047] (metformin), [0055] (metformin HCl), [0058] and [0062], for example. No new matter is being added by these amendments. Entry of the amendments is respectfully solicited.

Withdrawn claims 9-12, directed to other ISIS compounds not elected for prosecution in this application, have been canceled without prejudice to their inclusion in one or more related applications.

Applicants appreciate the courtesy of the personal interview at the U.S. Patent and Trademark Office among the undersigned attorney, Examiner Kim and S.P.E. Padmanabhan on March 28, 2006, as well as the follow-up telephone interview between the undersigned attorney and Examiner Kim of April 4, 2006. The foregoing amendments are identical to those sent to Examiner Kim in the form of a "Revised Draft Amendment" by facsimile on April 4, 2006, which Examiner Kim indicated were acceptable in a telephone message of April 6, 2006.

During the personal interview, the undersigned attorney questioned the date of the *Drug Launches* reference, asserted to have been published on June 8, 1988, but evidenced only with respect to a 2004 Abstract, well after the filing date of the present application. Examiner Kim indicated that she would check with the U.S. Patent and Trademark Office library staff and verify the publication date of the *Drug Launches* publication. During the follow-up telephone interview of April 4, Examiner Kim confirmed the publication date of this reference.

Also during the personal interview, the Examiners made clear that the *Drug Launches* reference was being relied upon as a printed publication, rather than as evidence that the product mentioned therein, namely, "NOVIAN FORTE," was in public use or on sale or generally known in the United States. Applicants refuted the availability of NOVIAN FORTE in the United States, based on a lack of any evidence provided by the U.S. Patent and Trademark Office

concerning such availability. GOOGLE® and YAHOO® searches for NOVIAN FORTE done in January, 2006 by the undersigned attorney produced no hits relating to this product.

NOVIAN FORTE was disclosed in *Drug Launches* as comprising various ingredients, including chlorhexidine gluconate, and was disclosed as being for the purpose of stimulation of hair growth and prevention of hair loss. Moreover, the undersigned attorney pointed out that chlorhexidine gluconate, present only in a 0.5% concentration, considerably less than the 3% concentration for reisogen in NOVIAN FORTE, was not likely responsible for the asserted properties of stimulation of hair growth and prevention of hair loss for the overall product, since chlorhexidine is known as an antiseptic or disinfectant, as set forth in the Krajcik Declaration submitted with the Amendment filed October 3, 2005. As noted in the Krajcik Declaration, chlorhexidine is not considered to be an insulin sensitivity increasing substance (ISIS) as disclosed and claimed in the present application.

The undersigned attorney then explained that chlorhexidine is a bisbiguanide, rather than a biguanide as previously claimed. The Examiners took the position that the term "biguanide" was considered a generic term which could include a bisbiguanide, such as chlorhexidine.

Although the undersigned attorney and Applicants strongly dispute this interpretation, to advance the prosecution of this application, claim 31, the only independent claim pending in the application, has been amended to identify the ISIS as a biguanide having the indicated formula, and alkyl or aromatic derivatives thereof, or a salt thereof. Similarly, claim 34, depending from claim 31, recites the same formula but including specific preferred derivatives and salts thereof.

In view of the formula recited in claims 31 and 34, the biguanide cannot be chlorhexidine, a bisbiguanide, which is set forth in the *Drug Launches* reference, assuming only for the sake of argument that the *Drug Launches* reference is a valid prior art reference. Based on the telephone message from Examiner Kim of April 6, the Examiners agreed with this position.

Based on the distinctions between the presently claimed invention and *Drug Launches* as the primary reference, the rejection under 35 U.S.C. § 103(a) of claims 31-37 over *Drug Launches* has been overcome, as has the rejection of claims 38-44 as being unpatentable over *Drug Launches* in view of Lurie U.S. Patent 6,075,005.

Reconsideration and withdrawal of the rejections and an early Notice of Allowance are respectfully solicited.

Respectfully submitted,

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April 11, 2006
(Date)

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